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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/668,573

09/23/2003

Jonathan R. Coppeta

17509-0068

3038

29052 7590 07/02/2007
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EXAMINER

MACNEILL, ELIZABETH

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

07/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/668,573

Applicant(s)

COPPETA ET AL.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-29, 35, 36 and 39-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-29, 35, 36 and 39-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/11/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendments submitted 11 May 2007.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 14-18,20-29, 35,36, and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Eppstein et al (US 6,692,456).

Eppstein teaches an array of discrete microtubes (a, Fig 23a and 23b), each defining a reservoir (b, Fig 24), a release formulation wholly contained within the reservoir (Fig 24), a rupturable covering (c), and means for rupturing the covering/barrier material (e) and positively displacing the release formulation (a). As to claims 16-18,20,24, The expanding material (e/a) is activated by heat (see Col 6 line 58-Col 7 line 10). As claim 21, Col 11 line 43; claim 27, Col 19 line 44; as to claim 28, this claim is a product-by-process claim and is given little patentable weight as it must result in a structural difference between the prior art and the invention; claim 29, Fig 25; claim 39, see claim 46.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 19 and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krulevitch et al (US 7,025,323) in view of Santini Jr et al (US 5,797,898).

Krulevitch teaches an array of discrete microtubes (97) defining a reservoir (86-90), a release formulation (103), and means for dispensing the release formulation (81-85) by positive displacement of a barrier material (98-102) by an expanding material (81-85) by application of heat from a resistive heating element (81'-85'). See Figs 7A and 7B.

Krulevitch does not disclose the material of the microneedles being made of a metal, or a rupturable metal foil covering over the distal end of the microneedles.

Santini discloses a microreservoir array which is covered by a metal foil where the array is made of a biocompatible material (copper or gold, for example). It would have been obvious to one of ordinary skill in the art at the time the invention was made to place a metallic cover over the microneedles in order to prevent leakage of the reservoirs or contamination of the reservoir contents. Regarding claim 20, copper is considered "reactive." Regarding the defects to facilitate rupture, the bonding of the metal layer would inherently create stress concentrations in the metal foil along the edge of the microneedle. Claim 28 is a product by process claim which is given little patentable weight.

3. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eppstein as applied to claims 14 and 16 above, and further in view of Theeuwes (US 4,111,202).

Eppstein teaches the limitations of claim 16 as above, but do not teach the use of a semi permeable membrane which allows water or another liquid to diffuse into the expanding material in order to displace and expel the drug formulation.

Theeuwes teaches an osmotic drug delivery system with a semi permeable membrane which allows water or another liquid to diffuse into the expanding material in order to displace and expel the drug formulation (Fig 4)

It would have been obvious to one of ordinary skill in the art at the time the invention Was made to combine the osmotic delivery system of Theeuwes with the micro needle array of Eppstein in order to facilitate expansion of the expandable member without electronics.

Response to Arguments

4. Applicant's arguments with respect to claims 14-18,20-29, 35, 36, and 39-41 have been considered but are moot in view of the new ground(s) of rejection.

5. Applicant's arguments filed 11 May 2007 regarding Krulevitch and Santini over claims 19 and 52-47 have been fully considered but they are not persuasive. Applicant has argued that there would be no reason to combine the covering of Santini with the needles of Krulevitch. The examiner's reason for combining the two teachings, to prevent leakage or contamination is not persuasive to the applicant because Krulevitch teaches an alternate means for preventing leakage. However, this would not prevent

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contamination because molecules could pass into the device. Additionally, the device of Krulevtich would no longer be limited to molecules of a certain charge if the covering of Santini was used. Therefore, there would be a convincing reason to apply the covering of Santini. The rejection is maintained.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

Ellyth
Marshall
10/25/07

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons